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10/507,385	09/09/2004	Teizo Yoshimura	4239-64104-02	8908

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/507,385	YOSHIMURA, TEIZO	
	Examiner	Art Unit	
	Maria Leavitt	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1-7, 10 drawn to a method for screening of an agent that induces maturation of an immature macrophage or an immature dendritic cell comprising contacting the immature macrophage or an immature dendritic cell expressing DDR1 with an antibody, chemical compound, or small molecule and measuring activation of p38MAP or Shc .

II. Claims 1-6, 8-10, drawn to a method for screening of an agent that induces maturation of an immature macrophage or an immature dendritic cell comprising contacting the immature macrophage or an immature dendritic cell expressing DDR1 with an agent and measuring expression of a cytokine or a chemokine.

III. Claims 11-22 drawn to a method for inducing maturation of an immature macrophage or an immature dendritic cell comprising contacting the immature macrophage or an immature dendritic cell expressing DDR1 with a DDR1-activating agent.

IV. Claims 23-25 drawn to a method for producing an antigen presenting macrophage or dendritic cell.

V. Claims 26-30 drawn to a method for modifying expression of a cytokine or a chemokine in a subject.

VI. Claims 31-38 drawn to a method of activating a neutrophil or a lymphocyte.

VII. Claims 39-45 drawn to a method of altering leukocyte migration.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

"If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-VII appears to be that they are methods for activation of DDR1 by a DDRl-activating agent which induces the maturation of a dendritic cell precursor, for example a monocyte, into a macrophage or a dendritic cell. Moreover, the methods teach that contacting a dendritic cell precursor with an antigen, in addition to a DDR1- activating agent, can induce the maturation of the dendritic cell precursor into an antigen-presenting dendritic cell. Thus, in the claimed methods, the activation of DDR1 can enhance antigen presentation to T cells and enhance T cell responses in a subject. However,

prior art has described a functional role for activators of the DDR1 in the developing cerebellum facilitating granule neuron axon outgrowth toward establishing proper connections with Purkinje neurons. (Bhatt et al., Genes Dev, 2000 Sep 1; 14(17):2216-28, Abstract). Therefore, the technical feature linking the invention of groups I –VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

This application contains claims directed to more than one species of the generic invention. Generic claims will be examined as they correspond to the selected groups. Currently claims 1, 11, 23, 26, 31, and 39 are generic, for example. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PTC Rule 13.1

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Restriction.

Should Groups I or II be elected, a species restriction is further required under 35 U.S.C. 121 and 372**, wherein a species election(s) must correspond to an elected group as indicated above**.

This application contains claims directed to the following patentably distinct species: **an antibody, a chemical compound, or a small molecule**.

1) Applicant is required to choose one specifically named **agent** as recited in claim 2

The species are independent or distinct because there are methods comprising agents having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes or chemical compounds (e.g., a chemical compound is chemically synthesized, and antibody is elicited *in vivo* against an antigenic response)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

1a) If applicant elects an antibody as an agent, Applicant is required to choose one specifically named **antibody** as recited in claims 4 and 5, from the following species:

anti-DDR1a and anti-DDR1b

The species are independent or distinct because they comprises receptors with different functions as a they are encoded by different genes as the results of alternative splicing

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

This application contains claims directed to the following patentably distinct species: **P38MAP kinase or Shc.**

2) Applicant is required to choose one specifically named **enzyme** as recited in claim 7.

The species are independent or distinct because there are enzymes comprising different structures and having different physical properties and biological functions as the result of being

coded by different genes (e.g., DDRlb is the LXNPXY motif that corresponds to the consensus binding motif for the She phosphotyrosine binding (PTB) domain).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

This application contains claims directed to the following patentably distinct species: **interleukin-6, interleukin -8, interleukin -10, interleukin -12, macrophage inflammatory protein-lα, interleukin-lβ, tumor necrosis factor-α, or monocyte chcemoattractant protein-1.**

3) Applicant is required to choose one specifically named **chemokine or cytokine** as recited in claim 9.

The species are independent or distinct because there are molecules comprising different structures and having different physical properties and biological functions as the result of being coded by different genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

Should Groups III be elected, a species restriction is further required under 35 U.S.C. 121 and 372, **wherein a species election(s) must correspond to an elected group as indicated above.**

4)This application contains claims directed to the following patentably distinct species: **granulocyte-macrophage-colony stimulating factor, tumor necrosis factor-α, interleukin-lβ, lipopolysaccharide, phytohemagglutinin, fetal calf serum or a combination thereof, a DDRl-activating antibody and a nucleic acid encoding DDR1b operably linked to a promoter.**

The species are independent or distinct because there are methods comprising agents comprising different structures and having different physical properties and biological functions as the result of being coded by different genes (Tumor necrosis factor-**α** is an immunoregulatory cytokine capable of inducing viral expression in cells chronically infected with the human immunodeficiency virus; **Fetal Calf Serum** Induces generic cell growth).

4) Applicant is required to choose one specifically named agent as recited in claims 13 and 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

This application contains claims directed to the following patentably distinct species: **Inducible or constitutive promoter.**

5) Applicant is required to choose one specifically named **promoter** as recited in claims 15 and 16.

The species are independent or distinct because there are methods comprising promoter genes having different chemical structures, physical properties, and biological functions as a

result of containing different expressed genes or chemical compounds (e.g., a constitutive promoter is not tissue specific).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

This application contains claims directed to the following patentably distinct species: **tumor necrosis factor-α, interleukin-4, lipopolysaechariде, granulocyte-macrophage-colony stimulating factor, CD40 ligand, or phorbol 12-myristate 13-acetate, or a combination thereof.**

6) Applicant is required to choose one specifically named **additional agent** as recited in claim 20.

The species are independent or distinct because there are methods comprising additional agents having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes or chemical compounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

Should Groups IV be elected, a species restriction is further required under 35 U.S.C. 121 and 372**, wherein a species election(s) must correspond to an elected group as indicated above.**

This application contains claims directed to the following patentably distinct species:

a protein, a polypeptide, a polysaccharide, a DNA molecule, a RNA molecule, a whole cell lysate, an apoptotic cell, or any combination thereof, a viral, bacterial or fungal antigen.

7) Applicant is required to choose one specifically named **antigen** as recited in claims 24 and 25.

The species are independent or distinct because there are methods comprising antigens having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes or chemical compounds (e.g., epitopes recognized in a bacteria and virus to induce an immunoresponse are exclusive and non overlapping)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

Should Groups V be elected, a species restriction is further required under 35 U.S.C. 121 and 372**, wherein a species election(s) must correspond to an elected group as indicated above**.

This application contains claims directed to the following patentably distinct species:

P38MAP kinase or Shc.

8) Applicant is required to choose one specifically named **enzyme** as recited in claim 27.

The species are independent or distinct because there are enzymes comprising different structures and having different physical properties and biological functions as the result of being

coded by different genes (e.g., DDRlb is the LXNPXY motif that corresponds to the consensus binding motif for the She phosphotyrosine binding (PTB) domain).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

This application contains claims directed to the following patentably distinct species: **interleukin-6, interleukin -8, interleukin -10, interleukin -12, macrophage inflammatory protein-lα, interleukin-lβ, tumor necrosis factor-α, or monocyte chcemoattractant protein-1.**

9) Applicant is required to choose one specifically named **chemokine or cytokine** as recited in claim 30.

The species are independent or distinct because there are molecules comprising different structures and having different physical properties and biological functions as the result of being coded by different genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

Should Groups VI or VII be elected, a species restriction is further required under 35 U.S.C. 121 and 372**, wherein a species election(s) must correspond to an elected group as indicated above**.

This application contains claims directed to the following patentably distinct species:

A neutrophil, a lymphocyte.

10) Applicant is required to choose one specifically named **cell** as recited in claims 31-33 and 44-45.

The species are independent or distinct because there are methods comprising cellular systems comprising cells with genes having different physical properties and biological functions (e.g., neutrophils phagocytic function, lymphocyte recognition of antigen).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

This application contains claims directed to the following patentably distinct species:

In vitro, in vivo.

11) Applicant is required to choose one specifically named **condition** as recited in claims 37-38 and 42-43.

The species are independent or distinct because there are methods comprising cellular systems comprising cells with genes having different physical properties and biological functions as a results of being regulated by different conditions (e.g., an isolated cell growing in *vitro* is not subjected to physiological regulations by hormonal secretion occurring in the *in vivo* conditions).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 11, 23, 26, 31, and 39 are generic.

In view of the distinction of species as set forth in the above paragraphs, it would be unduly burdensome for the examiner to search and examine more than one of the elected patentable distinct species of species listed above.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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